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Sepracor Inc. and  
University of Massachusetts*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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**SEPRACOR INC. and UNIVERSITY OF  
MASSACHUSETTS,**

**Plaintiffs,**

**v.**

**SUN PHARMACEUTICAL INDUSTRIES  
LTD., et al.,**

**Defendants.**

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) **Civil Action No. 07-4213 (MLC)(TJB)**  
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) **Hon. Mary L. Cooper, U.S.D.J.**

) **Hon. Tonianne J. Bongiovanni, U.S.M.J.**  
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**STIPULATION AND ORDER**

The Court, upon the consent and request of Plaintiffs Sepracor Inc. and University of Massachusetts (collectively, "Sepracor") and Defendants Mylan Pharmaceutical, Inc. and Mylan Laboratories, Inc. (collectively, "Mylan"), hereby acknowledges the following Stipulation and issues the following Order.

**STIPULATION**

1. This Court has subject matter jurisdiction over this patent infringement action (the "Action") and personal jurisdiction over Sepracor and Mylan. Venue is proper in this Court as to Sepracor and Mylan.

2. In this Action, Sepracor has charged Mylan with infringement of United States Patent Nos. 7,214,683 ("the '683 patent") and 7,214,684 ("the '684 patent") in connection with the submission of Abbreviated New Drug Application ("ANDA") No. 78-351 directed to generic tablets containing 5 milligrams of desloratadine per tablet to the U.S. Food and Drug Administration ("FDA").

3. In response to Sepracor's charges of patent infringement, Mylan has alleged certain defenses and counterclaims, including that the '683 and '684 patents are invalid and not infringed by the generic tablet product containing 5 milligrams of desloratadine per tablet that is the subject of ANDA No. 78-351. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses and counterclaims.

4. Mylan has not rebutted the statutory presumption that the '683 and '684 patents are valid and enforceable in this Action. This admission is without prejudice to Mylan's defenses and counterclaims that the '683 and '684 patents are invalid.

5. Mylan admits that the submission of ANDA No. 78-351 for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic tablets containing 5 milligrams of desloratadine per tablet within the United States before the expiration of the '683 and '684 patents was a technical act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Mylan's defenses and counterclaims that the '683 and '684 patents are invalid and/or that the product described by ANDA No. 78-351 does not infringe those patents.

6. Mylan has agreed that each of the defenses and counterclaims set forth in its Answer, Defenses, And Counterclaims, including the allegations and averments contained therein, should be dismissed, without prejudice.

7. Sepracor and Mylan make the following releases: (a) Mylan hereby releases and discharges Sepracor and its respective Affiliates, successors, assigns, directors, officers, employees, agents and customers from all causes of action, demands, claims, damages and liabilities of any nature, whether known or unknown, arising from or in connection with this Action, or the '683 patent and/or '684 patent, including, without limitation, all claims that Mylan has asserted or could have asserted in this Action; (b) Sepracor hereby releases and discharges Mylan and its Affiliates, successors, assigns, directors, officers, employees, agents and customers from all causes of action demands, claims, damages and liabilities of any nature, whether known or unknown, arising from or in connection with this Action, or the '683 patent and/or '684 patent, including without limitation, all claims that Sepracor has asserted or could have asserted in this Action; and (c) neither Sepracor or Mylan, nor any of their Affiliates or agents shall institute any new litigation with respect to the '683 patent, the '684 patent, or U.S. Patent Nos. 7,211,582; 5,731,319 and 5,595,997, and any other patents owned by Sepracor or its Affiliates that would be infringed by the manufacture, having manufactured, and/or marketing of any Generic Desloratadine Product, including any continuations, continuations-in-part, divisionals, reissues or reexaminations thereof (collectively the "Desloratadine Patents") against any products covered by ANDA No. 78-351 or any Mylan ANDA covering any plain (i.e., not rapidly dissolving) tablet product that contains desloratadine as the sole active ingredient and that is approved for marketing in the United States of America (collectively the "Generic Desloratadine Products"). Notwithstanding any of the above, nothing in this Stipulation shall prevent Sepracor or Mylan from instituting litigation against the other party involving a product other than a Generic Desloratadine Product, in which event nothing in this Stipulation shall prevent: (a) Sepracor from asserting in such litigation that such other product or products

infringe any of the Desloratadine Patents or other patents, or (b) Mylan from asserting in such litigation that any of the Desloratadine Patents or other patents are not infringed, invalid and unenforceable.

**ORDER**

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Sepracor and Mylan, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 78-351 constituted a technical act of infringement of the '683 and '684 patents under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by the parties regarding the presumptive validity of the '683 and '684 patents and/or whether the product described by ANDA No. 78-351 infringes those patents.
2. Mylan's defenses and counterclaims with respect to the '683 and '684 patents are hereby dismissed, without prejudice.
3. Mylan, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet product containing 5 milligrams of desloratadine per tablet that is the subject of ANDA No. 78-351 during the life of the '683 and '684 patents, including any extensions and pediatric exclusivities, except pursuant to a license and/or sublicense agreement, as applicable, or other authorization by Sepracor, unless all of the claims of the '683 and '684 patents are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.


4. Sepracor and Mylan each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Sepracor and Mylan for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve this Action between Sepracor and Mylan. Each party shall bear its own fees and costs in connection with this Action, including attorney fees.

7. The Clerk of the Court is directed to enter this Stipulation And Order forthwith.

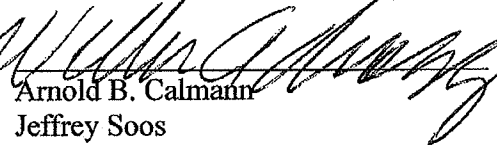
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*Counsel for Defendants  
Mylan Pharmaceuticals, Inc. and  
Mylan Laboratories, Inc.*

**SO ORDERED:**

This \_\_\_\_ day of \_\_\_\_\_, 2009

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**HONORABLE MARY L. COOPER  
UNITED STATES DISTRICT JUDGE**